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10/691,518	10/24/2003	Eyal Zolotariov	27021	7426
7590	07/10/2006			
			EXAMINER	
			GOLLAMUDI, SHARMILA S	
		ART UNIT	PAPER NUMBER	
			1616	

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/691,518	ZOLOTARIOV ET AL.
	Examiner	Art Unit
	Sharmila S. Gollamudi	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-41 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-24 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 and 21 contain the trademark/trade name Witepsol. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a carrier and, accordingly, the identification/description is indefinite.

Claim 21 is directed to a composition further comprising a hard fat Witepsol H15. Claim 24 is directed to Witepsol H15 in an amount of 0-23% and depends on claim 23. Claim 23 depends on claim 21 and thus Witepsol cannot be present in a weight percent of 0 since claim 21 requires Witepsol H15.

Claim 40 recites “The suppository of claim for use...” which is indefinite since it unclear what claim 40 depends from.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 11, 25-26, 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Wunderlich et al (5,387,415).

Wunderlich et al discloses a composition comprising 20 % gelatin, 15% glycerin, and 65% aloe juice. The composition is compressed into a pellet form.

Note with regard to the recitation “suppository” a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In instant case, suppository is given weight in that it must be a dosage form that is capable of being inserted into the body. Wunderlich’s pellet is capable of being inserted in the body. The examiner cites US 5,635,520 as art of interest to demonstrate the art’s use of the term “suppository”. Uda discloses the use of suppository administration including solid suppositories, semi-solid suppositories such as ointment/gel/jelly suppositories, and liquid suppositories for a high concentration of drug that does not undergo first-pass metabolism. See

column 18, lines 15-25 and abstract. Thus, it can be seen the term “suppository” relates to administration, “insertion” into the body cavities such as the rectum rather than imparting a structural limitation.

With regard to claims 25-26 and 40, the intended use of a product is not given patentable weight unless it imparts a structural limitation and in the instant case it does not.

Claims 1, 3, 25, 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Trenzeluk et al (4,857,328).

Trenzeluk discloses a formulation comprising the extract from the dried leaves of the Aloe Vera plant in an amount of 3% to 50%; a preservative in the amount of sulfathiazole in the amount of 5% to 20%; zinc oxide as a inert pigment in the amount of 5% to 16%; and petrolatum being 14% to 87% as the oil base. See column 4, lines 45-53.

Note with regard to the recitation “suppository” a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In instant case, suppository is given weight in that it must be a dosage form that is capable of being inserted into the body. Trenzeluk’s pellet is capable of being inserted in the body. The examiner cites US 5,635,520 as art of interest to demonstrate the art’s use of the term “suppository”. Uda discloses the use of suppository administration including solid suppositories, semi-solid suppositories such as ointment/gel/jelly suppositories, and liquid suppositories for a high concentration of drug that does not undergo first-pass metabolism. See

Art Unit: 1616

column 18, lines 15-25 and abstract. Thus, it can be seen the term “suppository” relates to administration, “insertion” into the body cavities such as the rectum rather than imparting a structural limitation

With regard to claims 25 and 40, the intended use of a product is not given patentable weight unless it imparts a structural limitation and in the instant case it does not.

Claims 1-2, 4-6, 9-10, 25-26, 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulte (4,708,873).

Schulte discloses a method for promoting the healing of an abnormal, ulcerated necrotic tissue on skin or mucous membrane of a patient which comprises applying topically to the affected area of the patient an amount of biphenamine and an amount of aloe vera effective to further promote wound healing. See column 2, lines 19-30. Schulte discloses that the term “aloe” refers to the sticky, viscous juice from the plant. See column 1, lines 53-30. Example 5 discloses a suppository comprising 0.070% biphenamine HCl, 15.37% sodium stearate, 69.15% glycerin, 15.37% aloe vera.

With regard to claims 6 and 9-10, the method in which sodium stearate is made does not hold patentable weight since the claims are directed to a product that requires the component sodium stearate. Note MPEP section 2113, “even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Further with regard to claims 9-10, it is the

Art Unit: 1616

examiner's position that since the same final component, sodium stearate, is used, the same amount of sodium carbonate and stearic acid would have been used.

With regard to claims 25, the intended use of a product is not given patentable weight unless it imparts a structural limitation and in the instant case it does not.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25, 27, 29-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Mermelstein et al (20030170325).

Mermelstein et al disclose a composition for vaginal dryness in a gel form or a suppository form. See [0011]. Example 17 discloses a composition comprising 0.10-25% aloe vera gel, 62-96% water, SMC, 0.30-25% chamomile, vitamin E, propylene glycol, jojoba oil, methyl paraben, propyl paraben, and imidazolidinyl urea. Mermelstein discloses to provide a suppository form, the water is with polymol (wax), which is a mixture of 43.4 % polyglycerin-6 octylmyristate, 14.4 % polyglyceryl-6 octahydroxystearate and 19.1 % pharmaceutical grade cocoa butter. [0083]. Mermelstein also discloses the wax in the formulation may be replaced with polyoxyethylene glycol having molecular weight between about 400 and about 6000. [0085].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulte (4,708,873) in view Chernomorsky (4,797,392).

Schulte discloses a method for promoting the healing of an abnormal, ulcerated necrotic tissue on skin or mucous membrane of a patient which comprises applying topically to the affected area of the patient an amount of biphenamine and an amount of aloe vera effective to further promote wound healing. See column 2, lines 19-30. Example 5 discloses a suppository comprising 0.070% biphenamine HCl and 15.37% aloe vera in a suppository base of 15.37% sodium stearate and 69.15% glycerin. Schulte teaches use of unmodified aloe or concentrated, isolated solids. See column 3, lines 20-40.

Schulte does not teach the instantly claimed suppository base.

Chernomorsky teaches an anorectal composition comprising chlorophyllin complex with a base including suppository bases for . See abstract. The reference teaches the suppository base may be a hydrophobic or hydrophilic base. See column 3, lines 20-30. Chernomorsky teaches a base comprising 70% glycerin, 20% gelatin, 9% water, and 1% chlorophyllin complex.

Chernomorsky also teaches a polyethylene glycol suppository base wherein a combination of 60% PEG 400 and 40% PEG 8000 is taught and a Witepsol base.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Schulte and Chernomorsky and utilize the instant suppository base. One would have been motivated to utilize a base comprising glycerin and gelatin if one desired to produce a hydrophilic suppository base rather than the oleaginous base taught by Schulte. Therefore, it is *prima facie* obvious for a skilled artisan to select an appropriate suppository bases that are known and routinely used in the art absent the unexpectedness of the instantly claimed base.

Secondly, although Chernomorsky teaches the use of 20% gelatin, it is obvious for a skilled artisan to manipulate the concentrations of the individual components in the base depending on the amount of active agent utilized. For instance, Schulte teaches the use of 15.37% aloe (about 16%) and thus utilizes 15.37% stearic acid and 69.15% glycerin. Thus, if one desired to formulate a hydrophilic base without any oil component, then one would replace the stearic acid with gelatin to provide a hydrophilic base.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulte (4,708,873) in view Mermelstein et al (20030170325)

Schulte discloses a method for promoting the healing of an abnormal, ulcerated necrotic tissue on skin or mucous membrane of a patient which comprises applying topically to the affected area of the patient an amount of biphenamine and an amount of aloe vera effective to further promote wound healing. See column 2, lines 19-30. Example 5 discloses a suppository comprising 0.070% biphenamine HCl and 15.37% aloe vera in a suppository base of 15.37%

Art Unit: 1616

sodium stearate and 69.15% glycerin. Schulte teaches use of unmodified aloe or concentrated, isolated solids. See column 3, lines 20-40. Schulte teaches aloe is used in an effective amount that further promotes wound healing and teaches it in various concentrations. See column 2, lines 35-50.

Schulte does not teach the instant concentration.

Mermelstein et al disclose a composition for vaginal dryness in a gel form or a suppository form. See [0011]. Mermelstein teaches aloe vera gel is used for wound healing and orally aloe vera gel is used as general tonic, anti-inflammatory agent and moisturizer and teaches the use of 0.10-25% of aloe vera gel in a suppository composition. See [0037] and Example 17.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Schulte and Mermelstein and utilize aloe in the instant concentration. One would have been motivated to do so with the expectation of success since Mermelstein teaches the use of aloe in an amount of 0.10-25% in a suppository for the same purpose.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulte (4,708,873) in view Mermelstein et al (20030170325) in further view of Borgman (5,536,743).

The teachings of Schulte have been set forth above. Example 5 discloses a suppository comprising 0.070% biphenamine HCl and 15.37% aloe vera in a suppository base of 15.37% sodium stearate and 69.15% glycerin. Schulte teaches use of unmodified aloe or concentrated, isolated solids. See column 3, lines 20-40.

The teachings of Mermelstein have been set forth above.

Schulte does not teach a glycerin and sodium stearate base but does not teach the instantly claimed concentration of glycerin.

Borgman teaches a metronidazole composition which may be in a suppository form which are known in the art. See column 9, lines 15-35. Borgman teaches glycerin and glycerinate gelatin based suppository. The suppository comprises about 85-90% glycerin congealed with gelatin with 5-10% sodium stearate. See column 22.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references and manipulate the concentration of the glycerin and sodium stearate. One would have been motivated to do so since Borgman teaches suppository bases are known in the art and exemplifies a glycerin-based suppository that comprising 85-90% glycerin and 5-10% sodium stearate. Thus, a skilled artisan would have been motivated to manipulate the amount of glycerin depending on the amount of sodium stearate desired in the composition.

Claims 27-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulte (4,708,873) in view of Maret (3,878,197).

Schulte discloses a method for promoting the healing of an abnormal, ulcerated necrotic tissue on skin or mucous membrane of a patient which comprises applying topically to the affected area of the patient an amount of biphenamine and an amount of aloe vera effective to further promote wound healing. See column 2, lines 19-30. Schulte discloses that the term "aloe" refers to the sticky, viscous juice from the plant. See column 1, lines 53-30. However, any form aloe may be used including extracts. See column 3, lines 20-30. Example 5 discloses a

Art Unit: 1616

suppository comprising 0.070% biphenamine HCl, 15.37% sodium stearate, 69.15% glycerin, 15.37% aloe vera.

Schulte does not teach the use of the aloe gel.

Maret teaches the process of preparing extracts of aloe vera. See abstract. Maret teaches the juice and gel of the aloe vera plant have been used for a long time in treating bites, burns, and other skin conditions. See column 1, lines 10-40.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Schulte and Maret and utilize both the aloe juice and aloe gel in the Schulte's composition. One would have been motivated to do so since Maret teaches that both aloe juice and gel have both been utilized to treat skin conditions such as burns, bites, etc. Thus, it would have been obvious to utilize the gel and juice for an additive effect. Further, one would have expected success since although Schulte prefers the juice, Schulte teaches the use of any form of the aloe extract.

Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trenzeluk et al (4,857,328) in view Takashima (4,279,909).

Trenzeluk discloses a formulation comprising the extract from the dried leaves of aloe vera, a preservative chosen from the group consisting of a sulfa derivative such as sulfathiazole and an alcohol amine, a skin softener such as an oil, and an oil soluble base. The aloe vera plant is in an amount of 3% to 50%; a preservative in the amount of sulfathiazole in the amount of 5% to 20%; zinc oxide as an inert pigment in the amount of 5% to 16%; and petrolatum being 14% to 87% as the oil base. See column 4, lines 45-53.

Trenzeluk does not teach the instantly claimed oil.

Takashima teaches an antiallergic method using compositions comprising substituted-carbonyl (lower) alkyl-2-benzothiazolinone compounds. See abstract. Takashima teaches various pharmaceutical forms including topical applications. Takashima teaches the use of “conventional” pharmaceutical carriers including base wax (e.g. cacao butter, polyethyleneglycol, Witepsol, white petrolatum, etc.). see column 6, lines 5-30.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Trenzeluk and Takashima and utilize the instant Witepsol base. One would have been motivated to substitute Trenzelik's petrolatum base with the instantly claimed Witepsol with the expectation of similar results and success since Takashima teaches that both Witepsol and petrolatum are functionally equivalent in that they both function as wax bases in topical compositions. Therefore, it is *prima facie* obvious for a skilled artisan to select an appropriate base that are known and routinely used in the pharmaceutical art for topical applications, especially for the treatment of symptoms such as inflammation, allergies, and itching.

With regard to claims 20-24, note the indefinite rejection. It is unclear the difference between Witepsol W45 and Witepsol H15 since applicant has only named the trade name and not the actual chemical component; thus it is considered obvious to utilize a mixture of hard fats with the trade name Witepsol absent the unexpectedness of the instant combination.

With regard to claim 22, Trenzeluk teaches the amount of dried extract may be utilized in an amount of 3-50% and exemplified 7.4%, which falls within the instantly claimed range.

With regard to claim 23, Trenzeluk teaches petrolatum in the amount of 14-87%, thus the substitution of petrolatum with the instantly claimed Witepsol would fall within the instant claimed range.

Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trenzeluk et al (4,857,328) in view in view Takashima (4,279,909) in further view of Urbin et al (3,639,579).

The teachings of Trenzeluk and Takashima have been set forth above. Trenzeluk teaches a topical composition comprising aloe for burns, psoriasis, sores, acne, etc. Takashima teaches an antiallergic composition for the use of “conventional” pharmaceutical carriers including base wax (e.g. cacao butter, polyethyleneglycol, Witepsol, white petrolatum, etc.).

The references do no teach the instantly claimed polyethylene glycols in the instant range.

Urbin teaches a pharmaceutical preparation to relieve itching and swelling comprising an enzyme in an ointment base. The ointment base comprises 30 grams of PEG-1540 and 50 grams of PEG-6000.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of above references and utilize the instant polyethylene glycol base. Firstly, one would have been motivated to substitute Trenzelik’s petrolatum base with the instantly claimed polyethylene glycols with the expectation of similar results and success since Takashima teaches that both polyethylene glycols and petrolatum are functionally equivalent in that they both function as wax bases in topical compositions. Secondly, it would have been obvious to utilize the instant PEG ratio since Urbin teaches the use of the PEG base in the instant

Art Unit: 1616

ratio for topical application of an active for itching and swelling. Therefore, it is *prima facie* obvious for a skilled artisan to select an appropriate base that are known and routinely used in pharmaceutical art for topical applications, especially for the treatment of symptoms such as inflammation, allergies, and itching.

With regard to claim 17, Trenzeluk teaches the amount of dried extract may be utilized in an amount of 3-50%, which encompasses the instant “about 20%”.

Conclusion

All the claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/691,518
Art Unit: 1616

Page 15


Sharmila S. Gollamudi
Examiner
Art Unit 1616